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Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002


Attention: Beverly Friedman

Dear Ms. Axelrad:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 7,097,834. The application was filed on July 27, 2010, under 35 U.S.C. § 156. The application was filed on August 10, 2010, under 35 U.S.C. § 156. Please note that patent term extension applications for U.S. Patent No. 7,411,050 and U.S. Patent No. 6,740,522 for BLA No. BL125320 for the human drug product PROLIA® (denosumab) were filed concurrently, pursuant to the provisions of 37 C.F.R. § 1.785.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term extension. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).


Mary C. Till

Senior Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Charles E. Van Horn
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RE: PROLIA® (denosumab)
Docket No.: FDA-2011-E-0659